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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,539	01/11/2002	Thomas R. Cech	015389-002630US	4930

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EXAMINER

LIETO, LOUIS D

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/044,539	Applicant(s) CECH ET AL.	
	Examiner Louis D Lieto	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response to the action on the merits was received on 9/21/2004. Claims 1-33 and 36-40 are pending in the instant application. Applicants canceled claims 34 and 35, amended claims 1 and 37, and added claims 38 and 40. The sections of title 35 U.S.C not included in this office action can be found in a previous office action. An action on the merits follows.

Priority

The objection over insufficient references for the parent applications is withdrawn, because the applicant has amended the specification to reflect the current status of the parent applications.

The original determination that claims 6-33 and 36 are not disclosed in the parent application 08/854,050 is maintained. Applicant's argument that the skilled reader will understand that the cell types listed in claims 6-33 and 36 of the instant application are specific species of the pending claims 1-5 and 39-40 is not found persuasive. As previously stated, the parent application 08/854,050, upon which priority is claimed, fails to provide adequate support under 35 U.S.C. 112 for claims 6-33 and 36 of this application. Claims 6-33 and 36 are to specific cell types that are not recited in the parent application 08/854,050. While the parent application 08/854,050 recites the generic cell of claims 1-5 and 39-40, this does not teach the specific species of cell types of claims 6-33 and 36 of this application

Information Disclosure Statement

A signed copy of the information disclosure statement should have been sent out with the previous office action. Another copy is provided.

Claim Rejections - 35 USC § 112

The rejection of original, amended, or new claims 1-33, and 36-40 under 36 U.S.C. 112, first paragraph, for scope of enablement, is maintained in part. Applicant's amendments and arguments filed 9/21/2004 have been fully considered but have not been found persuasive in overcoming the remaining grounds of rejection for reasons of record as discussed below.

The previous office action identified the following issues for reasons of the record: 1) lack of enablement for making and using fragments and variants of the polynucleotide SEQ ID NO:1, except for the full length form; 2) lack of enablement for isolating and using embryonic stem cells or other totipotent embryonic cells from mammals. Applicant's cancellation of claims 34 and 35 has overcome the rejection based on issue 2).

The rejection of record regarding issue 1 stands. The applicant argues that the rejection of claim 1 and its dependent is addressed by the amendment to claim 1. Applicant further states that the added language merely states what was previously inherent and that coverage for equivalent conditions and equivalent polynucleotides is retained.

In response, the previous office action pointed out that the specification while being enabling for full-length human telomerase reverse transcriptase protein does not reasonably provide enablement for fragments and variants thereof as broadly claimed. Without limitations defining the functions of such fragments and subsequences, one of skill in the art would not

know how they could be used and thus would also not know how to make them. The amino acid sequence of a polypeptide determines its structural and functional properties, and prediction of function is complex and well outside the realm of routine experimentation, because accurate prediction of a fragment's structure from mere sequence data is limited. Since information regarding the structural and functional requirements of the claimed fragments is lacking, it is unpredictable as to which fragments, if any, are usable. Further, while recombinant techniques are available, it is not routine in the art to screen large number of fragments where the expectation of obtaining any function is unpredictable. Thus one of skill in the art would require additional guidance, such as information regarding the expected function of the claimed fragments.

Applicant amended claim 1 to remove language referring to fragments and variants of telomerase reverse transcriptase protein from the claim. However, Applicant has added the new claims of 39 and 40, which continue to read on fragments of telomerase reverse transcriptase proteins. The examiner maintains the rejection, stated in the prior action, over claims 1-33, 36-38, and extends the rejection to claims 39, 40 because the claims continue to read on fragments and variants of telomerase reverse transcriptase proteins that would hybridize to SEQ ID NO:1. This interpretation of claim 1 is clearly shared by the applicant since the new dependent claims 39 and 40 specifically include fragments of telomerase reverse transcriptase proteins. Cancellation of claims 39 and 40 and amendment of claim 1 to indicate that the recombinant polynucleotide only contains a nucleic acid sequence encoding a full length human telomerase reverse transcriptase protein would be remedial.

Claim Rejections - 35 USC § 112(2)

The rejection of original claims 1-33, and 36-38 under 36 U.S.C. 112, second paragraph, for being indefinite, is withdrawn. Applicant's amendments to claim 1 filed 9/21/2004 have been fully considered and have been found to be persuasive in overcoming the grounds of rejection.

Double Patenting

The rejection of original, amended, or new claims 1-33, and 36-40 under the judicially created doctrine of obviousness-double patenting, is withdrawn. Applicant's amendments and arguments filed 9/21/2004 have been fully considered and have been found persuasive in overcoming the previous grounds of rejection for reasons of record as discussed below.

Applicants filing of a terminal disclaimer on 9/21/2004 with respect to US Patent NO: 6,475,789 is noted. Therefore, the rejection over US Patent NO: 6,475,789 has been withdrawn.

However, upon further consideration, new grounds of rejections under the judicially created doctrine of obviousness-double patenting are made in view of US Patent Application NO: 09/721,477, US Patent NO: 6,261,836 and US Patent NO: 6,337,200.

Claims 1, 2 and 40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 29, 31 and 32 of copending Application No. 09/721,477. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claims 1, 2 and 40, in the instant application, are rejected since they are the genus of the species of the invention of U. S. Patent Application No. 09/721,477. The patented claims are narrower in that they read on a human cell comprising the polynucleotide encoding hTERT, while the instant claims read on a mammalian cell. Claim 21 of US Patent Application No. 09/721,477 reads on at least 25 consecutive nucleotide contained in SEQ ID NO:1 that hybridizes to a DNA consisting of SEQ ID NO: 1. Claim 29 of the same application reads on a host cell transfected with the polynucleotide of claim 21. Claim 31 reads on where the cell of claim 29 is a eukaryotic cell. Claim 32 reads on where the cell of claim 29 is a human cell. Claim 1 in the instant application is to an isolated mammalian cell comprising a polynucleotide that hybridizes to a sequence complementary to SEQ ID NO:1. Claim 2 of the instant application limits the cell of claim 1 to a human cell. Claim 40 reads to where the mammalian cell is transfected with variants of SEQ ID NO:1. The pending claims 21, 29, 31 and 32, in U. S. Patent Application No. 09/721,477, read on the same material as claims 1-2, and 40, in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,3, 5 and 6 of U.S. Patent No. 6,261,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claims 1, 2 and 40, in the instant application, are rejected since they encompass the same patentable invention of U.S. Patent No. 6,261,836. Claim 1 of US Patent No. 6,261,836 reads on

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a polynucleotide that encodes full length, a fragment of, or variant of HTRT and that hybridizes to a DNA consisting of SEQ ID NO: 224. Claim 3 reads to an isolated or pure form of the polynucleotide of claim 1. Claim 5 reads to an isolated cell comprising the recombinant polynucleotide of claim 3. Claim 6 reads on where the cell is a eukaryotic cell. Paragraph 78 of the specification contemplates that the eukaryotic cell is a mammalian cell. The specification further incorporates by reference Bodnar et al., which contemplates where the eukaryotic cell is a human cell {Bodnar et al. (1998) Science 279:349-352}.

Claim 1 in the instant application is to an isolated mammalian cell comprising a polynucleotide that hybridizes to a sequence complementary to SEQ ID NO:1. Claim 2 reads to where the cell of claim 1 is a human cell. Claim 40 reads to where the mammalian cell is transfected with variants of SEQ ID NO:1. SEQ ID NO 224 of US Patent Application No. 09/721,477 is identical to SEQ ID NO:1 of the instant application. Claims 1, 3, 5 and 6 of U.S. Patent No. 6,261,836 encompasses claims 1, 2 and 40 in the instant application. Therefore, the patented claims render the instant claims obvious.

Claim 39 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10 and 11 of U.S. Patent No. 6,337,200. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claim 39, in the instant application, is rejected since it is the genus of the species of the invention of U. S. Patent No. 6,337,200. The patented claims are narrower since they limit the cell type to a human cell comprising the polynucleotide or fragments thereof encoding HTRT,

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while the instant claims read on a mammalian cell. Claim 1 of U.S. Patent No. 6,337,200 reads on a polynucleotide encoding a variant of HTRT, comprising a deletion of at least 10 amino acids from region 192-323 or 415-450 of SEQ ID NO:2. Claim 10 reads on a cell comprising the polynucleotide of claim 1. Claim 11 reads where the cell of claim 10 is a human cell. Claim 39 of the instant application is to a mammalian cell encodes a HTRT having the amino acid sequence of SEQ ID NO:2 or fragment thereof. Claims 1, 10 and 11 of U.S. Patent No. 6,337,200 anticipate claim 39 of the instant application. The patented claims are species of the broader claim 39 of the instant application. It is well established that a species of a claimed invention renders the genus obvious. In re Schaumann , 572 F.2d 312, 197 USPQ 5 (CCPA 1978). Therefore, the patented claims render the instant claims obvious.

All claims free of the prior art of record.

No claims allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy J Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with,

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Dr. Louis D. Lieto
Patent Examiner
Art Unit 1632

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', is written below the printed name and title.